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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/530,980 | 10/26/2005 | Martin Alan Lee | 41577/314737 | 9249 |

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| EXAMINER |
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CHUNDURU, SURYAPRABHA

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| ART UNIT | PAPER NUMBER |
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1637

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03/17/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

1. The Applicants' response to the office action field on December 02, 2009 has been considered and acknowledged.

Status of the application

2. Currently claims 43, 46, 48-69, 87-88 are pending under examination. Claims 1-42, 44-45, 47, 70-86 are cancelled. Applicants' arguments and the amendment have been fully considered and deemed unpersuasive for the reasons that follow.

Response to arguments:

3. With regard to the rejection of claims 43, 48-53, and 57-69 under 35 USC 102(b) as being anticipated by Higuchi, Applicants' arguments were fully considered and found unpersuasive. Applicants argue that Higuchi does not teach a DNA binding agent which can absorb fluorescent energy from the fluorescent label on the probe and assert that Higuchi teach two different signaling systems with the use of binding agent and a probe. The arguments were found unpersuasive because Higuchi (see page 5, line 34-44) explicitly teach the use of a binding agent in the amplification reaction in addition to a probe labeled with a flurophore and a quencher, wherein the labeled probe hybridizes to the amplified target and the probe hydrolysis separates bound and unbound probe and the fluorescence of unbound probe is detectably distinct from the bound probe and the fluorescence from the binding agent enables the detection that the amplification occurred and the fluorescence of the probe indicates amplification- this clearly teach that when the probe binds to the amplified target the binding agent interacts with the amplified product and generates amplification signal in conjunction with the labeled probe that is distinguishable with the fluorescence of the unbound probe. Thus it is clear that Higuchi does

teach signal amplification system using both a binding agent and a probe in the same reaction mixture, accordingly the rejection is maintained.

5. With regard to the rejection of claims 43, 46, 48-69, 87-88 under obviousness type double patenting over claims in patent 6,833,257 in view of Higuchi, Applicants' arguments were fully considered and found unpersuasive. As discussed above, Higuchi does teach the use of binding agents such as daunomycin in conjunction with a labeled probe and as discussed in the rejection it is obvious to modify the claimed invention with the use of a binding agent such as daunomycin. Accordingly the rejection is maintained.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637